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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,061	03/29/2006	Mitsuhiro Haraguchi	P28015	9213
7055 7590 05/21/2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			EXAMINER ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1614	
			NOTIFICATION DATE	DELIVERY MODE
			05/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary

Application No.

10/538,061

Applicant(s)

HARAGUCHI ET AL.

Examiner

Lezah W. Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06 Dec 2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Amendment filed February 20, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Double Patenting – Duplicate Claims

Applicant is advised that should claims 3-5, 10 and 13 be found allowable, claims 8-9, 11-12 and 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102 - Anticipation

1) Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeuchi et al. (US 5,624,962). The rejection is maintained in regards to claims 1 and 3-14.

Applicant argues the reference does not disclose the invention in claims 1 and 6 as presently claimed and every element is not disclosed in the reference as set forth in the claims. Takeuchi disclose ophthalmic compositions, which contain epinephrine. In

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contrast the compositions of the present invention is directed to oral surgery or dental treatment. Moreover the compositions of the instant claims exclude catecholamine (epinephrine). This argument is not persuasive.

The compositions of the reference may be used not only for ophthalmology but also in the oral cavity. Furthermore claim 6 does not recite the limitation that the compositions must be used in the oral cavity. Epinephrine is one of the drugs that may be delivered by the delivery system; it is not an essential ingredient in the compositions of the reference, therefore, it may be excluded.

2) Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Pan et al. (US 5,912,007). The rejection is maintained in regards to claim 6-7 and withdrawn in regards to claims 1-5 and 8-14.

Applicant argues the compositions of claim 1 and agent of claim 6 are intended to exclude a polysaccharide or a cross-linking agent, in view of the language "aqueous solution" in claim 1 and the "consisting of" language in claim 6. This argument is not persuasive.

In regards to claim 6 "consisting of", this claim is interpreted to be open. The claims as written are interpreted to mean, "comprising a compound selected from". The "consisting of" language precedes a Markush group and is not considered a transitional phrase. Therefore the compositions may comprise other components besides antihistamines.

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3) Claims 1, 3-7, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lapidus (US 5,543,148). The rejection is maintained and applied to claims 8-9, 11-12 and 14.

Applicant argues Lapidus discloses a gel composition and claim 1 is directed to an aqueous solution for oral surgery or dental treatment. Claim 6 includes the phrase "consisting of", which would exclude certain ingredients of Lapidus, e.g., gelling agents. This argument is not persuasive.

In regards to claim 1, the compositions of the reference comprise water and therefore are aqueous solutions. A solution is defined by Merriam-Webster as "an act or the process by which a solid, liquid, or gaseous substance is homogeneously mixed with a liquid or sometimes a gas or solid". This definition encompasses the gels of the instant claims. As for the use, intended use carries not weight in determining patentability because the compositions of the reference and the compositions of the instant claims are substantially the same and therefore may be used for the same purposes such as dental treatment. In regards to claim 6 "consisting of", this claim is interpreted to be open language. The claim as written is interpreted to mean, "comprising a compound selected from". The "consisting of" language precedes a Markush group and is not considered a transitional phrase. Therefore the compositions may comprise other components besides antihistamines.

Claims 1 and 3-14 are rejected.

No claims allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

